MAY - 9 2005

510(k) SUMMARY K050786

Applicant:

Mölnlycke Health Care
826 Newtown Yardley Rd.
Newtown, PA 18940

Contact Person:

John Clay
Regulatory Affairs Officer

Tel.: 267-685-2078
Fax: 267-685-2010

Device Name:

Proprietary Name:	Barrier® Surgical Gowns
Common/Usual Name:	Surgical Gowns
Device Classification:	Class II – 21 CFR 878.4040

Substantial Equivalence:

For the purpose of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Mölnlycke Health Care considers the BARRIER® Surgical Gowns are substantially equivalent in composition, function and intended use to the previously marketed BARRIER® Surgical Gowns.

Intended Use:

BARRIER® surgical gowns are intended for single use to be worn by the Surgical Team Members in the operating room during surgical procedures to protect both the patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.

Description:

The BARRIER® Surgical Gowns have been designed with an assortment of fabrics and have been on the market for a number of years cleared under predicate 510(k) notifications. BARRIER surgical gowns have been developed for general surgical procedures and for procedures which represent possible exposure to bloodborne pathogens and other potentially infectious materials which require increased levels of protection.

The following chart highlights the current BARRIER surgical gown families and the predicate 510(k) notifications under which they are currently marketed.

Description	Predicate 510(k)
BARRIER® Standard and Standard Fabric Reinforced Surgical Gowns	K760903
BARRIER® Extra and Ultra Protection Gowns	K760903
BARRIER® Extra and Ultra Protection Plus Surgical Gowns	K932731
BARRIER® Surgical Gown II and BARRIER® Surgical Gown II , Fabric Reinforced	K920996
BARRIER® Fluid Protection Plus Surgical Gowns	K990395
BARRIER® Urology Gown	K760903

Summary of Testing:

BARRIER® Surgical Gowns have been evaluated using the ANSI/AAMI PB-70:2003 Standard. ***(Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities)*** The chart represents the AAMI levels claimed for each gown family.

Description	**Level of Protection according to AAMI**
BARRIER® Standard and Standard Fabric Reinforced Surgical Gowns	Level 2
BARRIER® Extra and Ultra Protection Gowns	Level 3
BARRIER® Extra and Ultra Protection Plus Surgical Gowns	Level 4
BARRIER® Surgical Gown II and BARRIER® Surgical Gown II , Fabric Reinforced	Level 3
BARRIER® Fluid Protection Plus Surgical Gowns	Level 3
BARRIER® Urology Gown	Level 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. John Clay
Regulatory Affairs & Quality Officer-US
Mölnlycke Health Care
826 Newtown-Yardley Road, Suite 300
Newtown, Pennsylvania 18940

Re: K050786
Trade/Device Name: BARRIER® Surgical Gowns
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 19, 2005
Received: April 22, 2005

Dear Mr. Clay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050786

Device Name: BARRIER® Surgical Gowns

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy MD

(Division Sign-Off)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

(510(k) Number: K050786